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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,168	09/10/1999	TOSHIMITSU ISHIKAWA	724-P10-2589	2333

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EXAMINER
NGUYEN, HELEN

ART UNIT	PAPER NUMBER
1617	9

DATE MAILED: 01/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/393,168	Applicant(s) ISHIKAWA ET AL.	
	Examiner Helen Nguyen	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment of paper no. 8, filed November 29, 2001, is acknowledged.

Claims 1 and 17-20 are amended.

Claims 1-20 are pending and presenting for examination with elected species B drawn to water-soluble dietary fiber.

In view of the amendment of paper no. 8, filed November 29, 2001, claims 1-20 stand rejected as indicated below.

Specification objection

The objection on page 12, Table 2, the term "gymnema" is made moot by the amendment of paper no. 8.

Claim rejection- 35 USC § 112

The rejection of claims 17-20 under 35 USC 112, second paragraph is made moot by the amendment of paper no. 8.

Claim rejection- 35 USC § 102 (b)

The rejection of claims 1-20 under 35 USC 102 (b) as being anticipated by Miskel et al. (US Patent No. 3,851,051) is made moot by adding a limitation of "medicinal liquid is in the form of a suspended stock solution which is homogenized" in claims 1, 19 and 20.

In view of the amendment of paper no. 8, the rejection under 35 U.S.C. 112, first paragraph set forth in the previous office action of paper no. 6, filed May 29, 2001, has been considered, but they are not persuasive. Therefore, the rejection under 35 U.S.C 112, first paragraph is maintained and new grounds of rejection are applied for the reasons as follows:

Claim rejection

❖ The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> Claims 1-4, 19 and 20 are rejected under 35 U.S.C. 112, first

paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants claim a dietary fiber, however nowhere in the specification is disclosed any example of a specific dietary fiber.

- Applicants argue that one of ordinary skill would know what agents constitute dietary fibers. However, Applicants are there own

lexicographers as to what agents constitute dietary fibers, including what range of fibers are considered dietary fibers. That is, one of ordinary skill would not know whether Applicants intend to include lawn grass as a dietary fiber.

❖ The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Miskel et al. (US Patent No. 3,851,051) in view of Lacy et al. (US Patent No. 6,096,338).

Miskel et al., see Example 1 column 6, teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited-oil solubility (diphenhydramine). No dispersion stabilizer and fat and oil material or oil-soluble material is present.

Further, Miskel et al., see Example 50, teach a soft capsule comprising a water-soluble dietary fiber (apple pectin), a material of limited oil-solubility (glycerin) and a fat and oil material or oil-soluble material (vitamin E).

Lastly, Miskel et al., see Example 43, teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited oil-solubility (sodium saccharin). No dispersion stabilizer and fat and oil material or oil-soluble material is present.

Miskel et al. do not teach a homogenous mixture of the medicinal liquid in the soft capsule.

Lacy et al. teach a soft capsule containing a drug carrier system (title; abstract; column 14, lines 52-58, lines 61-63; and column 22, line 24). Lacy et al. also teach that homogeneity of a pharmaceutical composition allows controlled production of a uniform product (column 14, lines 29-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to homogenize the ingredient of Miskel et al. to achieve the beneficial effect of having a uniform product in a soft capsule in view of Lacy et al.

Claims 1-20 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point

out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on M-F (9:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Edward J. Webman can be reached at (703) 308-4432 or her supervisor, Minna Moezie can be reached at (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Helen Nguyen
Patent Examiner

January 17, 2002